Drug Importation: Would the Price Be Right?
Bill Number:
Hearing Date: February 17, 2005, 10:00 am
Location: SD430
Witness:
Dr. Robert Goldberg
Manhattan Institute, New York, NY
Senior Fellow
Testimony

Mr. Chairman.
Members of the Committee

My name is Robert Goldberg. I am director of the Center for Medical Progress for the Manhattan Institute for Policy Research in New York City. Thank you for the opportunity to testify. I will focus my comments on the impact of price controls on our competitiveness in biotechnology and our ability to invest in the genomic revolution that will allow Americans to receive cost-effective and personalized medicine for a wide range of diseases.

Drug importation is the importation of price-controlled medicines. It is therefore a form of price controls. I assume we are setting the aside the reality that price controls create shortages. As Americans demand more drugs a lower prices it will cause a run on Canada and our northern neighbor will not be America's drug store for long. And because Europe's inventory of medicines is tightly regulated as well, it too will not be a large and safe source of price controlled medicines. By the time any importation bill is passed, there won't be a lot of medicines to import.

Congress should oppose drug importation for several reasons.

First, it simply supports the protectionist policies of Europe. The regulation of prescription drugs in Europe and Canada are barriers that keep our innovative drugs down and out and protect less innovative companies that are not globally competitive. Europe and Canada consistently under price American medicines.

Price controls involves setting a reimbursement policy that first, delays to the market through prolonged price negotiation. For example five years after it's first European launch in Europe, the first targeted drug for breast cancer, Herceptin is only available in 70 percent of the continent. New drugs like Avastin for cancer, Humira for rheumatoid arthritis and Xolair for asthma have yet to be launched in most European countries.

Second, even when new drugs are made available they are priced beneath American prices and patient access is restricted.. In Australia, patients with leukemia and Alzeheimer's have to sign contracts giving the government the right to take away breakthrough medicines when bureaucrats think they don't need them. In Great Britain and the Netherlands, drugs for cancer and asthma that are standard therapy in America

are strictly rationed. And in all cases, the reimbursement rates for the drugs are far below what the biotech companies get in America.

At the same time, these governments pay premium prices for their countries own branded generic medicines. In Germany for example, they spend more on brand name generic medicines as a percentage of drug expenditures to the exclusion of newer medicines developed by American firms for the same diseases. Instead that money is used to prop up less efficient German firms that are less innovative and unable to compete globally. The German price control system protects domestic firms at the expense of more cost-effective and globally competitive American products. Australia similarly devotes more of their pharmaceutical dollar to generic drugs that are 90 percent of the price of brand drugs through their protectionist schemes.

Thanks to America's free market pricing, US biotech and pharmaceutical firms invest more relative to Europe. In 2003, American biotech and pharmaceutical firms increased their R&D investment by 16 percent compared to a 2 percent decline in Europe. Today, Europe pharma companies spend less than half of their R and D in Europe, down from 73 percent in 1990. While Europe has more biotech companies than America, we have 75 percent of all biotech revenues worldwide, 75 percent of all R&D expenditures and 80 percent of all key biotech patents.

Indeed, a day after Dr. Daniel Vasella the CEO of the Swiss-based Norvartis Pharmaceuticals and Senator Kennedy opened the Novartis Institute of Biomedical Research, in Cambridge, MA. Dr. Vasella said." There's no doubt that growth and profitability in a market-place help determine where research investment goes",
In a separate interview Dr. Vasella went on to say "Any government under pressure could do things that are shortsighted. We've seen the effect in Europe -- less investment in R&D and less progress in treating diseases like cancer. Many Europe-based companies are focusing increasingly on the U.S. market. As a result of price controls, European consumers are heading toward second-class citizenship when it comes to access to medicine,"

While Europe's price controlled pain may be our gain, ultimately I believe the continent and the entire world can benefit from our commitment to medical innovation and should embrace our market-based approach to improve their economic and physical well-being. Indeed, it is part and parcel of our entrepreneurial and innovative character as a nation that Americans have avoided price controls as a cost-saving measure. Instead, we have shown that we can save money by investing health care dollars by improving quality, and investing more money on the most valuable and cost-effective medical technologies available. Time and again, that has meant spending more on prescription drugs, which at 11 percent is still the smallest part of our health care budget.

Since the advent of penicillin, new medicines have produced the biggest gains in well-being and life expectancy compared to most other medical goods and services. The more we spend on new medicines, the more we save in money and in lives. As Columbia University economist Frank Lichtenberg has shown, over the past 30 years, each

generation of new medicines reduces what it costs to treat disease, increases productivity and lengthens our lives. For every dollar Medicare will spend on new medicines in the future, it will save eight on hospitals, physicians and home health care.

Let me digress for a second to discuss the claim that me-too medicines exist and that we can save research and health care dollars by eliminating what we spend on them.
The majority of follow-on drugs were in clinical development before the breakthrough drug for that disease was approved. In addition, one-third of follow-on drugs for a disease receive FDA's priority rating. Most follow-on drugs have different mechanisms of actions, side effect profiles. Finally, as a number of studies have shown, formulary limitations on the elderly, based on the assumption that all medicines are alike make seniors sicker and to lead more doctor office visits, more emergency room visits and more hospitalizations per year. In Australia and Germany, patients are routinely denied access to the newest medicines, even those such as Gleevec or Herceptin that have known disease targets and genetic tests that can identify for whom the medicines work. Hence, common cost-containment strategies based on the me-too medicine myth are associated with higher health care costs and poorer health.

This me-too medicine myth flows from the belief that most drug development is imitative or merely the easy part of bringing medicines to market. As a result, price control supporters claim – without evidence -- that it is cheap to develop new medicines or that government does all the research and that drug companies simply market what government labs invent. That begs the question that if drug development is more like opening up a Dunkin Donuts franchise, why aren't more generic firms jumping into the game? Why do biotech venture capital firms demand such a high rate of return?

Indeed, critics claim that companies don't need high profits to be innovative. That's ironic since under price controls in Europe, innovative drug development has been on the decline.

Using Dr. Lichtenberg's analysis as a starting point, the Manhattan Institute commissioned economists from the University of Connecticut to do a study to uncover the impact of European and VA type price controls on medical innovation and access to new medicines in the United States over the next 25 years. A copy of the full report is available here today and on the Manhattan Institute website. The researchers found that R&D spending will drop by nearly 40% over the next two decades, resulting in a loss of nearly $300 billion in R&D and 277 million life years.

Given the negative impact on future investment, the decision to impose or import price controls comes at a critical time in the course of medical progress. I believe that the impact of price controls on our well being would be greater than can be imagined because the scientific opportunities that await are so exciting and so significant. Further, they often originate in small companies with no revenues. Taking medicine to the next level of targeted drug development will require a complete transformation of the discovery and development platform and billions in new investment each year.
Smaller biotechnology firms -- many of which have pharmaceutical firms as venture

partners -- will lead the way in developing the next generation of targeted medicines. Thirty of the 34 drugs approved by the FDA last year came from such companies and fite the targeted medicine profile. Indeed, the era of the blockbuster drug is over. All companies are investing in the development of medicines targeted to specific molecules that control how we respond to drugs and to the different ways diseases are triggered. In this fundamental respect, all companies large and small are starting from scratch.

This will lead to more cost-effective medicine and better health in two ways. First, gene-based diagnostics will be able to determine what drugs that are on the market now work best for which patients. Contrary to the popular belief that there are me-too medicines, most people respond differently to the same medicine or need different drugs to obtain the same outcomes. My daughter, whose life was saved by the last of five drugs given to her for an eating disorder is a case in point. We will have an array of genetic tests to guide such decisions.

Second, new drugs will be tailored to smaller groups of patients – or even a single person – based on their genetic response or adverse reaction to drugs as well as to differences in how diseases unfold. We have seen that with cancer drugs but the same will apply to drugs for diabetes, arthritis and heart disease.

Here too, American companies have been leading the world in this next medical revolution investing nearly $4 billion in gene-based tools for researching and developing treatments. Price controls and importing price controls will only discourage the personalized medicine revolution. This revolution will save more money and lives than any across the board price cut might generate. That’s because the cost of poorly caring for patients with Alzheimer’s, cancer, Parkinson’s, blindness, stroke and others is much more expensive than the personalized and targeted medicines that will treat. Put another way, treating or curing a disease with a new medicine is always cheaper than the disease itself.

In the final analysis, the best way to make new medicines less expensive is to reduce the cost of developing them. As more companies move toward targeted medicines and as the FDA embraces scientific reforms that encourage their development, companies will be able to reduce the time it takes from target identification to launch from more than 10 years to between three and five and slash research and development costs by 75 percent. That will save companies and consumers billions of dollars a year in drug costs without undermine incentives for investment or access to new medicines. The Manhattan Institute has established a 21st Century FDA Task Force that seeks to create a path towards personalized medicine. We welcome the opportunity to assist the committee in reducing the cost of drug development.

Price controls will not make medicines more affordable, they will make them unavailable and undiscoverable. We can pay for new medicines as we always have, by taking the money we used to spend on intensive care units, polio wards, on TB hospitals, on HIV hospice, on body bruising chemotherapy, on nursing homes and spending it to cover more people with miracle cures. And we can pay for them by transforming the way we

discover and develop new medicines by sustaining our investment in genetic science. Let’s embrace the future and avoid the mistakes of the past.